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10/087,035	02/27/2002	Robert Kincaid	1001011076-1	6480

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EXAMINER	
SMITH, CAROLYN L	

ART UNIT	PAPER NUMBER
1631	

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Agilent Technologies, Inc
Legal Department, DL429
Intellectual Property Administration
P.O. Box 7599
Loveland, CO 80537-0599

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/087,035	KINCAID, ROBERT	
	Examiner	Art Unit	
	Carolyn L. Smith	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 October 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-11,22,27,28 and 31-41* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-11,22,27,28 and 31-41* is/are rejected.

7)☒ Claim(s) *9 and 38* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendments and remarks, filed 10/3/05, are acknowledged. Amended claims 1, 4-7, 9-11, 22, and 27-28 and new claims 31-41 are acknowledged.

Applicant's arguments, filed 10/3/05, have been fully considered but they are not deemed to be persuasive. Rejections and/or objections not reiterated from the previous office actions are hereby withdrawn. The following rejections and/or objections are either reiterated or newly applied. They constitute the complete set presently being applied to the instant application.

Claims 1-11, 22, 27-28, and 31-41 are herein under examination.

Claim Objections

Claims 9 and 38 are objected to because of the following informality: Claims 9 (line 3) and 38 (last line) contain improper commas. Appropriate correction is required.

Claim Rejections - 35 USC § 112, first paragraph

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-11, 22, 27-28, and 31-41 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled

in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

NEW MATTER/LACK OF WRITTEN DESCRIPTION

This rejection is necessitated by amendment.

Applicants point to written support for claims 1, 22, and 27 in paragraphs [0064], [0072], and Figure 2. These portions of the original disclosure do not provide adequate written support for "at least one probe specific for said curated sequence" (claim 1, lines 8-9), "said at least one vendor selected probe" (claim 1, penultimate line), "at least one of said vendor selected nucleic acid probes" (claim 22, last two lines and claim 27, lines 13-14).

Because the introduction of "at least one probe specific for said curated sequence" (claim 1, lines 8-9), "said at least one vendor selected probe" (claim 1, penultimate line), "at least one of said vendor selected nucleic acid probes" (claims 22 and 27) lack adequate written support in the specification, claims and/or drawings, as originally filed, these limitations are considered to be NEW MATTER.

Claim Rejections - 35 USC § 112, second paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 38-40 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

This rejection is necessitated by amendment.

Claim 38 (last line) recites the limitation "said customer selected array design parameters". There is insufficient antecedent basis for this limitation in the claim as there is no previous mention of this phrase. It is noted that claims 39 and 40 also have this phrase. Claims 39 and 40 are also rejected due to their dependency from claim 38.

Claim 39 recites the phrase "according to" which is vague and indefinite. It is unclear what parameters and to what degree these parameters must be met to be considered to be "according to". Clarification via clearer claim wording is requested.

Claim Rejections – 35 USC §102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-11, 22, 27-28, and 31-41 are rejected under 35 U.S.C. 102(e)(1) as being anticipated by Zhou et al. (US 2003/0120432 A1).

This rejection is necessitated by amendment.

The priority date relied upon for the above mentioned patent application publication comes from provisional applications.

Copies of the provisional applications are not included with this Office action, because the copies could not be readily obtained when the Office action was mailed. Should applicant

desire a copy of such a provisional application, applicant should promptly request the copy from the Office of Public Records (OPR) in accordance with 37 CFR 1.14(a)(1)(iv), paying the required fee under 37 CFR 1.19(b)(1). If a copy is ordered from OPR, the shortened statutory period for reply to this Office action will not be reset under MPEP § 710.06 unless applicant can demonstrate a substantial delay by the Office in fulfilling the order for the copy of the provisional application. Where the applicant has been notified on the PTO-892 that a copy of the provisional application is not readily available, the provision of MPEP § 707.05(a) that a copy of the cited reference will be automatically furnished without charge does not apply.

Zhou et al. disclose a method for generating a custom probe array design wherein a system receives user-selected identifiers (array design parameters) (abstract), as stated in instant claims 1, 6, and 22. Zhou et al. disclose the user selecting probe set identifiers from a corresponding list that correspond to a gene (paragraph 0009). Zhou et al. disclose a web portal processes inquiries regarding biological information and a user selects « probe set identifiers » which enable detection of nucleic acids and genes for microarray experiments (paragraph 0005) which represents a customer selecting at least one array design parameter and at least one gene of interest, as stated in instant claims 1, 22, and 27. Zhou et al. disclose the genomic portal system receives user-selected identifiers including sequence information, the system verifies probes corresponding to identifiers and generates a custom probe array design (paragraphs 0006 and 0008) and constructing and arranging arrays to detect and/or measure any one gene expression (paragraph 0007) which represents providing parameters to the vendor who curates the sequence and selects the probes specific for the curated sequence as mentioned in paragraph 0005, as stated in instant claims 1, 22, and 27. Zhou et al. disclose using remote vendor business systems

and servers (Figure 4, #404 and paragraph 0134), as stated in instant claims 1, 2, 22, 27, and 31. Zhou et al. disclose further generation including modifying or rejecting one or more user-selected probe array format factors including user-selected probe set identifiers and displaying this information to the user (paragraph 0010) which represents the vendor selecting at least one probe specific for the curated gene sequence, as stated in instant claims 1, 22, and 27. Zhou et al. disclose a method and system (vendor) enabling a number of users to share space on an array or enabling a number of users to share in ordering portions of a lot of catalog probe arrays for economical benefit (paragraphs 0005 and 0006), which represents the vendor providing at least one additional array design parameter including probe selection as well as layout parameters, as stated in instant claims 1, 5, 27, and 34. Zhou et al. disclose synthesizing the probe arrays (paragraph 0010) which represents completing the array design and fabricating the array, as stated in instant claims 1, 22, 27, and 28. Zhou et al. disclose the user may select many probe array format factors such as number of probes, dimensions of probes, maximum number of probes representing one or more genes, substrate material (paragraph 0009) which represents the user selecting "other" customer selected array design parameters, as stated in instant claims 33-36. Zhou et al. disclose the user may select geographic dispersion of probe sets (paragraph 0009) which represents a customer selected array design layout and probe parameters, as stated in instant claims 5, 34, and 35. Zhou et al. disclose using a probe set with controls, as stated in instant claims 7 and 36. Figure 14 shows a graphical user interface for providing options and design selections (paragraph 0039), as stated in instant claims 8 and 37. Figure 15 shows a graphical user interface for providing one or more custom probe array designs or probe set designs (layouts) (paragraphs 0010 and 0040) which represents visual display of array layout of

at least one customer selected array design parameter, as stated in instant claims 9 and 38. Zhou et al. disclose receiving probe set identifiers that identify potential probes and verifying probe sets of verified probes (paragraph 0007), which represents some probe selection by a vendor, as stated in instant claims 1 and 27. Zhou et al. disclose displaying the custom probe array design to the user via graphical user interface and receives a user selection specifying acceptance, modification, or rejection of the design (abstract and Figure 15), as stated in instant claims 10, 11, 39 and 40. The user acceptance of array design represents completion of the design by the vendor, as stated in instant claims 1, 2, 22, 27, and 31. The user modification of the design represents completion of the array design by the customer, as stated in instant claims 1, 3, 22, 27, and 32. Zhou et al. disclose providing the user with the accepted or modified custom probe array (abstract). Zhou et al. disclose using arrays for genes and nucleic acids (Figure 2 #230), as stated in instant claims 4, 22, and 27. Zhou et al. disclose researchers using microarrays to determine which genes are expressed in certain cells or organs, extracting biological information, and designing follow-up experiments (paragraph 0004). Zhou et al. disclose the probe set identifiers may be selected by the user from a predetermined list where each item may correspond to an EST, gene, splice variant, or protein (paragraph 0009) which represents selecting at least one gene of interest and probe parameter for said gene, as stated in instant claim 27. Zhou et al. disclose systems, methods, and computer program products to address these needs, such as allowing the user to select probe identifiers that may be associated with probe sets of one or more probes that are capable of detecting genes of interest, which are then correlated with data and/or products to be provided to the user (paragraph 0006), as stated in instant claim 27. Figures 7A and 10 show displaying and providing genomic data, sequence data, expression data,

and various other forms of information to the user (paragraphs 0030 and 0034), as stated in instant claim 27. Zhou et al. disclose synthesizing probes on a substrate (paragraph 0090), as stated in instant claim 28. Zhou et al. disclose selecting substrate material or design and synthesized probe arrays (paragraph 0010), as stated in instant claim 28. Zhou et al. disclose constructing probe arrays to detect or measure one or any combination of biological information including gene expression, genotype, cells, cellular membranes, and organelles (paragraph 0007) which represents an in situ array, as stated in instant claim 41.

Thus, Zhou et al. anticipate the instant invention.

It is noted that Applicant filed a Declaration under 37 CFR 1.131 to document his conception of systems and methods for gene-based array design before July 16, 2001. Upon review of the provisionals of US 2003/0120432 A1, it is noted that Provisional application No. 60/301,298 ('298), filed 6/25/01, contains all of the limitations of the instant claims. Therefore, the prior art reference US 2003/0120432 A1 is still applicable for the 35 USC 102 rejection above.

Applicants argue that the '298 provisional application does not teach a vendor curate and select probes for a gene of interest provided by a customer. This statement is found unpersuasive as the instant claims state "at least one gene of interest". Furthermore, the '298 application discloses "Initial Offerings" that are available to customers (page 19) that contain designs for various genomes which represent one or more gene of interest. Furthermore, there is a custom design based on sequences and instructions provided by the customer as well as a subset design based on probe sets of existing designs (page 2) wherein the subset design represents a selection

of probes for at least one gene of interest, as stated in the instant claims. The vendor manufactures the chip (page 4) which represents curating a sequence for said at least one gene of interest. Applicants argue that the customer identifies probes that have been pre-selected by the vendor to include on the array. This statement is found irrelevant as pre-selection or the lack thereof is not recited in the claims. Selection has taken place, as recited by the claims. Furthermore, subset design represents further selection. The instant claims do not mention "new probes" as argued by Applicants. Applicants argue if there are no pre-selected probes for a gene of interest to a customer, then the methods disclosed by Zhou et al. do not curate a sequence for the customer selected gene and then select probes for that curated sequence. This statement is confusing as Applicants just argued that there were pre-selected probes in the provisional. This statement is also found unpersuasive because the argued limitations are not actually recited in the instant claims. The instant claims refer to "at least one gene of interest" which is disclosed by '298, as already discussed above. The instant claims also recite the curating of a sequence for said at least one gene of interest. It is noted that the terms "curating" and "sequence" can be interpreted broadly, such that the sequence can be any sequence, be it a probe or a gene. Applicants' arguments are considered unpersuasive such that the 35 USC 102 rejection remains as necessitated by amendment.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Papers related to this application may be submitted to Technical Center 1600 by facsimile transmission. Papers should be faxed to Technical Center 1600 via the PTO Fax Center. The faxing of such papers must conform with the notices published in the Official Gazette, 1096 OG 30 (November 15, 1988), 1156 OG 61 (November 16, 1993), and 1157 OG 94 (December 28, 1993) (See 37 CFR §1.6(d)). The Central Fax Center number for official correspondence is (571) 273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carolyn Smith, whose telephone number is (571) 272-0721. The examiner can normally be reached Monday through Thursday from 8 A.M. to 6:30 P.M.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached on (571) 272-0718.

Any inquiry of a general nature or relating to the status of this application should be directed to Legal Instruments Examiner Tina Plunkett whose telephone number is (571) 272-0549.

MARJORIE A. MORAN
PRIMARY EXAMINER
Marjorie A. Moran
12/1/05

November 28, 2005